Response
Serial No.: 10/626,341
Confirmation No.: 9160
Filed: 24 July 2003
For: AMIDE-FUNCTIONAL POLYMERS, COMPOSITIONS, AND METHODS

Remarks

The Office Action mailed 6 February 2006 has been received and reviewed. No claims having been canceled, amended, or added, the pending claims are claims 1-58. Claims 8-58 having been withdrawn from consideration by the Examiner as being drawn to non-elected groups, the claims currently under consideration are claims 1-7

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-3 under 35 U.S.C. §102(b) as being anticipated by the abstract of JP 4-41423. This rejection is respectfully traversed.

Claim 1 recites "[a] reactive polymer comprising a non-terminal monomeric unit comprising a pendant ethylenically unsaturated group and copolymerized N-isopropylacrylamide." Claim 3 recites "[a] reactive polymer comprising: 1% by weight to 90% by weight of non-terminal monomeric units comprising a pendant ethylenically unsaturated group, based on the total weight of monomeric units; and 1% by weight to 99% by weight of copolymerized N-isopropylacrylamide, based on the total weight of monomeric units." Applicants respectfully submit that JP 4-41423 lacks a clear and unambiguous disclosure of polymers such as those recited in claims 1-3 having ***a pendant ethylenically unsaturated group***.

The Examiner specifically noted the disclosure of "ethylene glycol dimethacrylate" in the recitation "[i]n an example N-isopropylacrylamide (3.0g), butyl methacrylate (0.158g), ethylene glycol dimethacrylate (0.0288g) and tert.-butyl-peroxy-2-ethyl hexanoate (0.009g) were dissolved in 1,4-dioxane (3ml), bubbled with N2 for 10 mins., . . . and reacted at 80 deg.C for 12 hrs. to give ***a gel film***" (page 1 of English language abstract; underlining in original; bold added for emphasis). To the extent that the Examiner is implying that including a dimethacrylate (e.g., ethylene glycol dimethacrylate) as a comonomer in a free radical (e.g., peroxide initiated)

polymerization necessarily results in a pendant ethylenically unsaturated group, Applicants earnestly disagree.

JP 4-41423 provides no disclosure or suggestion that including ethylene glycol dimethacrylate as a comonomer in a free radical polymerization necessarily results in a pendant ethylenically unsaturated group. Further, the Examiner has failed to provide a convincing line of reasoning as to why including ethylene glycol dimethacrylate as a comonomer in a free radical polymerization would necessarily result in a pendant ethylenically unsaturated group. Moreover, JP 4-41423 discloses that the polymerization results in ***a gel film***. Applicants respectfully submit that the gel film can result from crosslinking as a result of both methacrylate moieties of an ethylene glycol dimethacrylate reacting under free radical polymerization conditions.

For at least this reason, Applicants respectfully submit that JP 4-41423 fails to anticipate claims 1-3.

The Examiner rejected claims 1-4 under 35 U.S.C. §102(b) as being anticipated by Kaetsu et al. (U.S. Patent No. 5,152,758). This rejection is respectfully traversed.

Claim 1 recites "[a] reactive polymer comprising a non-terminal monomeric unit comprising a pendant ethylenically unsaturated group and copolymerized N-isopropylacrylamide." Claim 3 recites "[a] reactive polymer comprising: 1% by weight to 90% by weight of non-terminal monomeric units comprising a pendant ethylenically unsaturated group, based on the total weight of monomeric units; and 1% by weight to 99% by weight of copolymerized N-isopropylacrylamide, based on the total weight of monomeric units." Applicants respectfully submit that Kaetsu et al. lack a clear and unambiguous disclosure of polymers such as those recited in claims 1-4 having ***a pendant ethylenically unsaturated group.***

The Examiner specifically noted the disclosure of a "crosslinking agent" in the recitation of "a hydrogel obtained by the alkali hydrolysis of a copolymer comprising N-isopropylacrylamide, an ionic monomer (preferably, an anionic monomer such as acrylic acid or

methacrylic acid) and a crosslinking agent. In producing such a hydrogel, N-isopropylacrylamide and an ionic monomer are copolymerized in the presence of a crosslinking agent, and the resulting copolymer is hydrolyzed with alkali. . . . Examples of the crosslinking agent to be present in the reaction system include ethylene glycol dimethacrylate, diethylene glycol dimethacrylate, triethylene glycol dimethacrylate and polyethylene glycol #200 dimethacrylate (produced by Shin Nakamura Kagaku Kogyo; number of ethylene units=4)" (column 3, lines 18-37). To the extent that the Examiner is implying that including a crosslinking agent (e.g., a dimethacrylate) as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group, Applicants earnestly disagree.

Kaetsu et al. provide no disclosure or suggestion that including a crosslinking agent as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group. Further, the Examiner has failed to provide a convincing line of reasoning as to why including a crosslinking agent as a comonomer in the polymerization would necessarily result in a pendant ethylenically unsaturated group. Moreover, Kaetsu et al. disclose that the polymerization results in hydrogel. Applicants respectfully submit that it is well known in the art that hydrogels typically include crosslinked polymers, as supported, for example, by Tanaka et al. (discussed herein below). Applicants respectfully submit that the hydrogel can result from crosslinking as a result of both methacrylate moieties of a dimethacrylate crosslinking agent reacting under polymerization conditions.

For at least this reason, Applicants respectfully submit that Kaetsu et al. fail to anticipate claims 1-3.

In view of the remarks presented herein above, reconsideration and withdrawal of the rejections under 35 U.S.C. §102 are respectfully requested.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 5-7 under 35 U.S.C. §103(a) as being unpatentable over Kaetsu et al. (U.S. Patent No. 5,152,758). This rejection is respectfully traversed.

The deficiencies of Kaetsu et al. as applied to claims 3 and 4 have been discussed herein above in response to the anticipation rejection based on Kaetsu et al. Claim 5 depends from claim 4. Applicants respectfully submit that claim 4 is patentable over Kaetsu et al. for at least the reasons presented herein above for the patentability of claims 3 and 4. In brief, Kaetsu et al. fail to disclose or suggest polymers such as those recited in claims 3 and 4 having ***a pendant ethylenically unsaturated group***.

Independent claim 6 recites "[a] reactive polymer comprising a polymeric backbone having at least three ethylenically unsaturated pendant groups and a plurality of pendant groups of the formula -C(O)NHCH(CH_3)$_2$ attached to the backbone." Again, Kaetsu et al. fail to disclose or suggest polymers such as those recited in claim 6 having ***at least three ethylenically unsaturated pendant groups***.

For at least these reasons, Applicants respectfully submit that claims 5-7 are patentable over Kaetsu et al.

The Examiner rejected claims 1-7 under 35 U.S.C. §103(a) as being unpatentable over Tanaka et al. (U.S. Patent No. 4,732,930) or Meier et al. (U.S. Patent No. 6,616,946 B1) or Kazakov et al. (U.S. Patent No. 2003/0044455 A1). This rejection is respectfully traversed.

"To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art and not based on applicant's disclosure." M.P.E.P. §706.02(j).

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness, for at least the reason that none of Tanaka et al., Meier et al., and Kazakov et al. disclose or suggest polymers such as those recited in claims 1-7 having pendant ethylenically unsaturated groups, as discussed herein below.

TANAKA ET AL.

Regarding Tanaka et al., the Examiner specifically noted the disclosure of a "crosslinking agent" in the recitation of "[a]n ionic gel formed by polymerization of isopropylacrylamide in the presence of an ion-containing monomer, a crosslinking agent and a suitable liquid medium" (abstract). "Representative crosslinking agents include N,N'- methylene-bis acrylamide, ethylene glycol dimethacrylate, glycerine triacrylate or divinylbenzene or the like" (column 2, lines 67 to column 3, line 1). To the extent that the Examiner is implying that including a crosslinking agent (e.g., a dimethacrylate) as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group, Applicants earnestly disagree.

Tanaka et al. disclose that "[g]el is a form of material between the liquid and solid state. It consists of ***a crosslinked network*** of long polymer molecules with liquid molecules trapped within the network" (column 1, lines 12-15; emphasis added). "***The crosslinking agent*** effects partial ***crosslinking of the polymerized isopropylacrylamide*** and provides a means to control the strength, swelling degree, phase transition temperature and the like of the non-ionic gel by changing the crosslinking density" (column 3, lines 6-10; emphasis added). "***The crosslinked polymerized product thus obtained***, which is insoluble in, and also not swelled in higher alcohol, is swelled in solvents such as water, dimethylsulfoxide, dimethylformamide, acetone, tetrahydrofuran, dioxane mixtures thereof and the like" (column 3, lines 21-25; emphasis added).

Tanaka et al. provide no disclosure or suggestion that including a crosslinking agent as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group. Further, the Examiner has failed to provide a convincing line of reasoning as to why including a crosslinking agent as a comonomer in the polymerization would necessarily result in a pendant ethylenically unsaturated group. Moreover, Applicants respectfully submit that it would be clear to one of skill in the art, in view of the disclosure of Tanaka et al., that unsaturated groups in a multi-functional crosslinking agent can be used in forming the crosslinked network in the polymerized product.

For at least this reason, Applicants respectfully submit that Tanaka et al. fail to disclose or suggest polymers such as those recited in claims 1-7 having pendant ethylenically unsaturated groups.

KAZAKOV ET AL.

Regarding Kazakov et al., the Examiner specifically noted the disclosure of crosslinking comonomers in the preparation of hydrogels. Kazakov et al. list exemplary cross-linkers "for all types of radical polymerization" (paragraph 50, page 4). To the extent that the Examiner is implying that including a crosslinker (e.g., a dimethacrylate) as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group, Applicants earnestly disagree.

Karzakov et al. provide no disclosure or suggestion that including a crosslinker as a comonomer in the polymerization necessarily results in a pendant ethylenically unsaturated group. Further, the Examiner has failed to provide a convincing line of reasoning as to why including a crosslinker as a comonomer in the polymerization would necessarily result in a pendant ethylenically unsaturated group. Moreover, Applicants respectfully submit that it would be clear to one of skill in the art, in view of the disclosure of Kazakov et al., that unsaturated

groups in a multi-functional crosslinker can be used in forming the crosslinked network in the polymerized product.

MEIER ET AL.

Meier et al. disclose "[p]olymeric hollow particles for delivery of an agent . . . that change permeability in response to a change in an external stimulus such as pH, temperature, light, ionic strength, electric field, magnetic field and/or solvent composition." (Abstract).

In one embodiment, Meier et al. disclose responsive hollow particles "made of appropriate stimulus responsive polymers. For example, a thermosensitive response may be observed for hollow particles of poly(N-isopropylacrylamide) (PNIPAM)." (Column 3, lines 35-63). "Illustrative of ***the many different types of temperature responsive polymers*** are polymers and copolymers of N-isopropyl acrylamide (NIPAAm)" (column 5, lines 19-22; emphasis added).

Meier et al. further disclosed that "[i]n one embodiment, the particles are made of ABA or BAB triblock or AB diblock amphiphilic copolymers, containing one or more hydrophilic A blocks and one or more hydrophobic B blocks, that self-assemble in water to form hollow particles. A or B, or both, may be a stimulus responsive polymer. Alternatively, a stimulus responsive polymer may be mixed with the self-assembling polymers to form hollow particles, or after formation of the hollow particles. The stimulus responsive polymer may be entrapped within the particles at the time of formation, or chemically or ionically coupled to the amphiphilic polymers forming the self-assembling hollow particles." (Column 8, lines 31-42).

Meier et al. further describe the hydrophilic and hydrophilic segments of such copolymers:

> The amphiphilic segmented copolymer includes at least one segment B that includes a hydrophobic polymer. Any of a number of hydrophobic polymers can be used, such as, but not limited to, polysiloxane such as polydimethylsiloxane and polydiphenylsiloxane, perfluoropolyether, polystyrene, polyoxypropylene , polyvinylacetate, polyoxybutylene, polyisoprene, polybutadiene, polyvinylchloride,

> polyalkylacrylate, polyalkylmethacrylate, polyacrylonitrile, polypropylene, PTHF, polymethacrylates, polyacrylates, polysulfones, polyvinylethers, and poly(propylene oxide), and copolymers thereof. (Column 9, lines 29-39).
>
> In addition to the hydrophobic segment B, the amphiphilic segmented copolymer includes at least one segment A which includes at least one hydrophilic polymer, such as, but not limited to, polyoxazoline, polyethylene glycol, polyethylene oxide, polyvinyl alcohol, polyvinylpyrrolidone, polyacrylamide, poly(meth)acrylic acid, polyethylene oxide-co-polypropyleneoxide block copolymers, poly(vinylether), poly(N,N-dimethylacrylamide), polyacrylic acid, polyacyl alkylene imine, polyhydroxyalkylacrylates such as hydroxyethyl methacrylate (HEMA), hydroxyethyl acrylate, and hydroxypropyl acrylate, polyols, and copolymeric mixtures of two or more of the above mentioned polymers, natural polymers such as polysaccharides and polypeptides, and copolymers thereof, and polyionic molecules such as polyallylammonium, polyethyleneimine, polyvinylbenzyltrimethylammonium, polyaniline, sulfonated polyaniline, polypyrrole, and polypyridinium, polythiophene-acetic acids, polystyrenesulfonic acids, zwitterionic molecules, and salts and copolymers thereof. (Column 10, lines 6-25).

As noted by the Examiner, polybutadiene is included among the 19 exemplary classes of hydrophobic polymers and copolymers thereof disclosed by Meier et al. for use as B segments (column 9, lines 29-39). However, Applicants note that poly (N-isopropylacrylamide) is not included among the 17 or more exemplary classes of hydrophilic polymers, salts, and copolymers thereof disclosed by Meier et al. for use as A segments (Column 10, lines 6-25). Although, Meier et al. recite "(lower alkyl) acrylamides and methacrylamides" among a list of 25 or more suitable hydrophilic monomers (column 10, lines 31-53), N-isopropylacrylamide is not specifically recited.

Thus, Applicants respectfully submit that Maier et al. fail to clearly and unambiguously disclose a segmented polymer that includes a polybutadiene segment and a poly(N-

isopropylacrylamide) segment. Further, to arrive at a segmented polymer that includes a polybutadiene segment and a poly(N-isopropylacrylamide) segment as suggested by the Examiner, one of skill in the art would be required to select polybutadiene from 19 classes of hydrophobic polymers; to further select "(lower alkyl) acrylamides and methacrylamides" from 25 or more suitable hydrophilic monomers; and even further to select N-isopropylacrylamide from an open-ended list of possible species of "(lower alkyl) acrylamides and methacrylamides." (a selection of one combination out of over 475 (19 x 25) possibilities). However, Meier et al. provide no guidance for one of skill in the art to make the combination suggested by the Examiner. Moreover, because butadiene can be polymerized in a 1,4-manner (e.g., to yield monomeric units of the structure $-CH_2-CH=CH-CH_2-$), a polybutadiene segment would not necessarily even provide pendant ethylenically unsaturated groups.

The Examiner further pointed to crosslinking agents (e.g., multifunctional (meth)acrylates) for segmented copolymers disclosed by Meier et al. (column 13, line 50 to column 14, line 13). As discussed above, Meier do not clearly and unambiguously disclose segmented copolymers that include N-isopropylacrylamide. Further, there is no disclosure or suggestion in Meier et al. that including a crosslinker such as a multifunctional (meth)acrylate as a comonomer in the polymerization would necessarily result in a pendant ethylenically unsaturated group. In addition, the Examiner has failed to provide a convincing line of reasoning as to why including a crosslinker such as a multifunctional (meth)acrylate as a comonomer in the polymerization would necessarily result in a pendant ethylenically unsaturated group. Moreover, Applicants respectfully submit that it would be clear to one of skill in the art, in view of the disclosure of Meier et al., that (meth)acrylate groups in a multi-functional (meth)acrylate crosslinker can be used in forming the crosslinked network in the polymerized product.

Finally, the Examiner pointed to the recitation in Meier et al. regarding introducing polymerizable groups at the end of or pendent from the growing segments (column 12, line 59 to column 13, line 19). Applicants note that this recitation is directed to segmented polymers in

general. Again, there is no clear and unambiguous disclosure of segmented copolymers that include N-isopropylacrylamide in Meier et al. Thus, there is no nexus between the general methods of introducing polymerizable groups recited in Meier et al. and segmented copolymers that include N-isopropylacrylamide.

For at least the above reasons, Applicants disagree with the Examiner's assertion that "it would have been obvious to one skilled in the art to select N-isopropylacrylamide copolymerize (*sic*) with the suitable multifunctional comonomers and crosslinking monomers, motivated the by reasonable expectation of success" (page 6, second paragraph of the Office Action mailed 6 February 2006). Applicants respectfully submit that Meier et al. fail to clearly and unambiguously disclose segmented copolymers that include N-isopropylacrylamide as discussed herein above. Further, Applicants respectfully submit that Meier et al. fail to provide the motivation for one of skill in the art to modify the teachings therein to arrive at the presently claimed invention.

In view of the remarks presented herein above, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

Request for Rejoinder

Claims 8-58 have been withdrawn by the Examiner from further consideration as being drawn to a non-elected invention. Because the restricted claims are directed to methods of making and using polymers containing polymerized NIPAAM, and compositions thereof, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement.

In the event the Examiner maintains the restriction requirement, Applicants respectfully request rejoinder of the non-elected claims.

For example, claims 8-14 are directed to methods of making polymers containing polymerized NIPAAM and a pendant ethylenically unsaturated group. Claims 44-56 are directed

to a method of using a polymer as recited in claim 1. Upon an indication of claim 1 being allowable, Applicants respectfully request that method claims 8-14 and 44-56 also be rejoined and examined pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Further, claims 24-33 are directed to compositions including reactive polymers as recited in claim 1. Thus, claim 1 is a linking claim. "Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability." M.P.E.P. §809. Upon an indication of claim 1 being allowable, Applicants respectfully request that composition claims 24-33 also be rejoined and examined pursuant to M.P.E.P. §809.

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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

May 8, 2006
Date

By: _____
Loren D. Albin
Reg. No. 37,763
Direct Dial (612) 305-1225

CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of May, 2006, at 1:16 p.m. (Central Time).

By: _____
Name: Rachel Gagliardi-Graham